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## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 12373580/JGC	<b>FOR FURTHER ACTION</b>	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416).
International Application No. <b>PCT/AU2003/001606</b>	International Filing Date (day/month/year) 2 December 2003	Priority Date (day/month/year) 2 December 2002
International Patent Classification (IPC) or national classification and IPC Int. Cl. <sup>7</sup> C07K 7/06, 7/08; A61K 38/04; A61P 9/00, 13/00, 25/00		
Applicant XENOME LTD et al		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 3 sheets, including this cover sheet.

☒ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of 2 sheet(s).

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand 25 March 2004	Date of completion of the report 11 June 2004
Name and mailing address of the IPEA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustalia.gov.au Facsimile No. (02) 6285 3929	Authorized Officer  <b>SWARUP CHATTERJEE</b> Telephone No. (02) 6283 2259

**I. Basis of the report**

1. With regard to the elements of the international application:\*
- ☐ the international application as originally filed.
- ☒ the description, pages 1, 3-30, 32-59, as originally filed,  
pages , filed with the demand,  
pages 2, 31, received on 1 June 2004 with the letter of 1 June 2004
- ☒ the claims, pages 60-67, as originally filed,  
pages , as amended (together with any statement) under Article 19,  
pages , filed with the demand,  
pages , received on with the letter of
- ☒ the drawings, pages 1/1, as originally filed,  
pages , filed with the demand,  
pages , received on with the letter of
- ☒ the sequence listing part of the description:  
pages 1-84, as originally filed  
pages , filed with the demand  
pages , received on with the letter of
2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.  
These elements were available or furnished to this Authority in the following language which is:
- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).
3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:
- ☒ contained in the international application in written form.
- ☐ Filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished
4. ☐ The amendments have resulted in the cancellation of:
- ☐ the description, pages
- ☐ the claims, Nos.
- ☐ the drawings, sheets/fig.
5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).\*\*

\* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

\*\* Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report

**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement****1. Statement**

Novelty (N)	Claims 1-37	YES
	Claims	NO
Inventive step (IS)	Claims 1-37	YES
	Claims	NO
Industrial applicability (IA)	Claims 1-37	YES
	Claims	NO

**2. Citations and explanations (Rule 70.7)**

The following documents were cited in the International Search Report:

D1: WO 2000/020444

D2: WO 2000/044769

Claims 1-37 are novel because neither D1 or D2 explicitly disclose  $\chi$ -conotoxins with peptides with sequences corresponding to SEQ ID NO 5 or 6, and in the case of SEQ ID NO 3 and 4, peptides  $\chi$ -MrIA,  $\chi$ -MrIB, Mar2 have been excluded from the scope of the claims as a result of the proviso. Mar 1 of D2 does fall within the scope of SEQ ID NO 3 and 4, but is not disclosed as a  $\chi$ -conotoxin peptide.

D1 discloses the  $\chi$ -conotoxin peptides  $\chi$ -MrIA and  $\chi$ -MrIB which are of close sequence homology to SEQ ID NO 5 and 6 of the current invention, and furthermore contemplates derivatives, including addition or substitution of amino acids. However D1 has not disclosed the specific modifications as in the current claims, and given the applicant has found certain unexpected advantages of SEQ ID NO 5 over  $\chi$ -MrIA (see page 7 lines 22-31 of the current application) and that the derivative according to SEQ ID NO 6 increases the binding affinity of the  $\chi$ -peptides, it can be acknowledged that claims 1-37 are inventive when compared to D1.

D2 discloses peptides which appear to be  $\alpha$ -conotoxins, in which case D2 teaches away from the  $\chi$ -conotoxins of the current application. D2 discloses Mar1 and Mar2 which are also of close sequence homology to SEQ ID NO 5 and 6, but, again they are  $\alpha$ -conotoxins, not  $\chi$ -conotoxins. Even if they were  $\chi$ -conotoxins, by using the same reasoning as for D1, given the unexpected advantages the applicant has discovered for these polypeptides claims 1-37 are inventive when compared to D2.

Claims 1-37 meet the requirement for industrial applicability.